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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/751,658	12/31/2000	Rolfe C. Anderson	1087.3A-1.1(37US4)	8815

33743 7590 08/28/2003

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EXAMINER
BEISNER, WILLIAM H

ART UNIT	PAPER NUMBER
1744	

DATE MAILED: 08/28/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/751,658	ANDERSON ET AL.	
	Examiner	Art Unit	
	William H. Beisner	1744	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 June 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *90-135* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *90-135* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *23* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. The information disclosure statement filed 29 May 2003 has been considered and made of record.

Claim Objections

2. Claim 97 is objected to because of the following informalities: The current copy of claim 97 indicates that it depends from itself. It appears that the claim should depend from claim 96 and will be treated as such. Appropriate correction is required.

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 90, 91, 132 and 133 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 6-8 of U.S. Patent No. 6,197,595 in view of Webster (US 4,858,883). Claims 6-8 of U.S. Patent 6,197,595 encompass a method of measuring and directing a known volume of a fluid sample within a microfluidic

device. While the method employs controllable valves, the instant claims require the use of a diaphragm valve. The reference of Webster (US 4,858,883) discloses that the use of diaphragm valves are known in microfluidic devices (See Figure 1). In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to employ a diaphragm valve in the method of the patented claims for the known and expected result of providing a means recognized in the art for achieve the desired result of controlling the flow of fluid within a microfluidic device.

3. Claims 92-116 and 134 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 6-8 of U.S. Patent No. 6,197,595 in view of Wilding et al.(US 5,498,392). Claims 6-8 of U.S. Patent 6,197,595 encompass a method of measuring and directing a known volume of a fluid sample within a microfluidic device. While the method employs controllable valves, the instant claims require the use of a sealable port and the use of nucleic acid reaction and detection techniques. The reference of Wilding et al. discloses a microfluidic device which includes a sample introduction port (51) and a plurality of nucleic acid reaction and detection structures (See the entire disclosure). In view of this teaching, it would have been obvious to one of ordinary skill in the art to employ the method encompassed by the patented claims to perform nucleic acid reactions and/or detections for the known and expected result of providing a known volume of sample material to the device.

4. Claims 117-131 and 135 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-58 of U.S. Patent No. 5,922,591 in

view of Wilding et al.(US 5,498,392). Claims 1-58 of U.S. Patent No. 5,922,591 encompass a device which is structurally similar to the device of the instant claims. The device of the patent claims includes at least two chambers connected by a common channel wherein each chamber includes a vent port and the device includes a controllable valve and an external pressure source for controlling the valve and the flow of fluid between the chambers and channel. The instant claims differ by reciting that the device includes a sealable inlet port. The reference of Wilding et al. discloses that it is known in the art to provide a microfluidic device with sealable ports for the introduction of sample and reagents into the fluidic system (See column 14, lines 11-37). In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the device of the patented claims with a sealable port for the known and expected result of providing a means recognized in the art for introducing sample and/or reagents into the sealed microfluidic reaction system.

Response to Arguments

5. Applicants' remarks filed with the response dated 16 June 2003 indicate that the instant claims overcome the 35 USC 112, second paragraph, rejections of record in view of the amendments made to the claims.

As a result, the 35 USC 112, second paragraph, rejections have been withdrawn.

Note, the office action dated 13 February 2003 also included rejection of the claims under nonstatutory double patenting (See sections 2-4 above). Applicants' remarks are silent as to these rejections.

Note Applicants previously argued (See the response filed 02 Dec. 2002) these rejections are improper because the claims of the instant application were subject to a restriction requirement in the parent application (08/671,928) of the application which issued as U.S. Patent No. 6,197,595.

Applicants' comments are not found to be persuasive for the following reason;

In this restriction requirement set forth in parent application 08/671,928), Group II consisted of claims 84-88 and Group IV consisted of claims 90-91. Claims 84-88 of Group II correspond to claims 1-5 of U.S. Patent No. 6,197,595. Claims 6-8 of U.S. Patent No. 6,197,595 were added during prosecution of application 09/294,700 and were not part of the claims of the original restriction requirement.

Conclusion

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Beisner whose telephone number is 703-308-4006. The examiner can normally be reached on Tues. to Fri. and alt. Mon. from 6:40am to 4:10pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert J. Warden can be reached on 703-308-2920. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

William H. Beisner
Primary Examiner
Art Unit 1744

WHB